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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,536	03/11/2004	Leah E. Appel	PC10270B	7842

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,536	APPEL ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 05/04/05, and Information Disclosure filed 7/18/05.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 07/18/05 was filed after the mailing date of the Non-final Office Action on 02/02/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-68 and 70-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 15-45, 47-49 and 51-67 of U.S. Patent No. 6,706,283 ('283). Although the conflicting claims

are not identical, they are not patentably distinct from each other because the '283 patent claims a controlled release dosage form, comprising: (a) a core comprising an osmotic agent and a low solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, at least a major portion of said drug being amorphous; (b) a water-permeable coating around said core having at least one delivery port therein, said coating controlling the influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port to said aqueous environment of use, said coating being non-dissolving and non-eroding during release of said drug; wherein said osmotic agent comprises a water-swellable hydrophilic polymer that is separate from said dispersion polymer; wherein said dosage form provides an AUC in a use environment that is at least 1.25-fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug; and wherein said drug in said solid dispersion exhibits non-crystalline character in x-ray diffraction analysis. Cellulosic polymer including hydroxypropylmethyl cellulose acetate succinate (hpmcas) is found in claims 16, 30 and 48. The dosage form can be in the form of a bead (multiparticulate) is found in claims 17 and 52. The osmotic agent and the solid dispersion are in respective discrete portions, or in first or second layer is found in claims 19-21. Therefore, one of ordinary skill in the art would expect the same controlled release osmotic dosage form results from the use of the instant invention given the claims of '283. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '283, which set out a similar

controlled release osmotic dosage form using the same ingredients, conditions, and techniques as claimed herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-68, 70-74 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerc et al. WO 96/36318.

Kerc discloses a pharmaceutical composition comprising a core containing amorphous drug dispersed in dispersion polymer, and a coating surrounding the core (page 4, 1st and 2nd paragraphs). The core further comprises surfactant, and water-soluble polymer such as polyvinylpyrrolidone (ID, and page 5, 2nd and 3rd paragraphs). Amorphous drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4th paragraph. Dispersion polymer includes hydroxypropylmethyl-cellulose (page 7, 1st paragraph). The composition can be prepared in granule (multiparticulate) form, and the granule can than be compressed into tablet (page 11, 5th paragraph, and examples).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-57, 60-72 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerc et al. WO 96/36318, in view of Wong et al. US 4,765,989.

Kerc is relied upon for the reason stated above. Kerc does not expressly teach the coating surrounding the core having at least one port as claimed in claim 49.

Wong teaches a device for administering water insoluble or a slightly water insoluble drug at a controlled rate (see abstract, and column 3, lines 28-34). The device comprises a drug core compartment surrounding by a water permeable coating having at least one passageway (column 5, lines 6-34, column 9, lines 33-50, and column 13, lines 65-68). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Kerc to include at least one passageway in the coating, because Kerc teaches a novel dosage for controlled release of water insoluble drug at a controlled rate, because Kerc teaches a dosage with improved solubility and dissolution rate, and because Wong teaches a device that can deliver a pH dependent beneficial agent, a device that maximizes the dissolution rate, a device that provides effective release of beneficial agent (columns 13-14), and a device that provides precise release rate of drugs that are difficult to deliver in the environment of use, while simultaneously maintaining the integrity and the character of the device (column 25, lines 48-58).

It is noted that the cited references do not teach the dosage form provides an AUC in a use environment that is at least 1.25 fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug. However, it is the position of the examiner that the dosage form of Kerc in combination with Wong would provide a similar AUC because the cited references recognize the advantageous results of dispersing the insoluble drug in a polymer to provide sustained/controlled release rate to obtain high bioavailability.

Claims 58, 59 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerc et al., in view of Wong et al., and Kigoshi et al. US 6,254,889.

Kerc and Wong are relied upon for the above reasons. The cited references are silence as to the teachings of dispersion polymer such as hpmcas.

Kigoshi teaches a solid dispersion dosage form of amorphous drug, wherein in the solid dispersion, the drug is dispersed in polymer including hpmcas (see abstract, and column 3, lines 18-33). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Ayer and Baichwal using the solid dispersion dosage form in view of the teaching of Kigoshi, because Baichwal teaches the use of medicament in amorphous form to achieve high bioavailability of insoluble drug (column 3, lines 9-18), because Ayer teaches dispersing drug in cellulosic polymer (column 10, lines 26-44), and because Kigoshi teaches the solid dispersion of amorphous drug can be formulated into granulating process, tabletting process, as well as coating process (column 5, lines 60 through column 6, lines 1-9).

Response to Arguments

Applicant's arguments filed 05/04/05 have been fully considered but they are not persuasive. Nonetheless, in view of new art found in the submitted IDS, the 103(a) rejection over Ayer, in view of Baichwal has been withdrawn.

Applicant argues that a disclaimer that disclaims the terminal portion of any patent issuing on the instant application is not needed, and that is because the (issued) double patenting reference, '283, will nominally expire twenty years from its date of filing, on the same date as any patent issuing on the instant application will expire. In response to the applicant's argument, there are at least two reasons for insisting upon a terminal disclaimer to overcome a judicially created double patenting rejection in a continuing application subject to a 20-year term under 35 U.S.C. 154(a)(2). First, 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process. Thus, 35 U.S.C. 154 does not ensure that any patent issuing will necessarily expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). Second, 37 CFR 1.321(c)(3) requires that a terminal disclaimer filed to obviate a judicially created double patenting rejection include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection. This requirement serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention (37 CFR 1.601(n)). *In re Van Ornum*, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Accordingly, a terminal disclaimer

under 37 CFR 1.321 is required in an application to overcome a judicially created double patenting rejection.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 07/18/05 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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